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REPLY TO: _____

May 2, 2007

REDACTED PUBLIC VERSION

VIA E-FILING AND HAND DELIVERY

The Honorable Sue L. Robinson
United States District Court
for the District of Delaware
844 North King Street
Wilmington, DE 19801

**Re: In re '318 Patent Infringement Litigation (consolidated)
Civil Action No. 05-356 (SLR)**

Dear Chief Judge Robinson:

During the pre-trial hearing before this Court on April 18, 2007, Plaintiffs moved to exclude the trial testimony of Dr. Michael Rainer, an Austrian doctor whom Defendants listed on their trial witness list. After hearing argument on the issue, the Court asked for further briefing on the question of whether "the purpose for which [Defendants] want[] to use this evidence was specifically and formally put at issue in this case so that everyone knew it was at issue and everyone had a full and fair opportunity to test." Ex. A., Pretrial Conf. Tr. at 64. The Court instructed Defendants to identify the evidence at issue and give the Court "a balanced view of what the record shows." *Id.* at 65.

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I. The Evidence At Issue

The documents, produced by Plaintiffs, that Defendants would like Dr. Rainer to authenticate and lay the foundation for are:

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- C. A 1997 article by Dr. Rainer published in *Drugs of Today*, vol. 33, No. 4, titled “Clinical Studies with Galantamine” (Ex. D, DX 169).**

This article was produced by Plaintiff Synaptech. In this article, Dr. Rainer states, *inter alia*, “[t]he notion that it might be possible to exploit the well-established central cholinergic effects of galanthamine for the treatment of AD can be traced back to the psychiatric ward at Ybbs a.d. Donau in Austria, where the first favorable case studies were reported in 1986.” Ex. D. at 00001. This document is relevant because it is confirmatory evidence that was published in a known journal that Dr. Rainer had the idea to use galantamine for Alzheimer’s disease at approximately the same time as Dr. Davis.

II. The Record Plainly Shows That The Purpose For Which Defendants Want to Use the Rainer Evidence Was Made Known To Plaintiffs Long Before The Parties’ Pretrial Submissions

Plaintiffs produced documents by Dr. Rainer, Defendants’ experts relied on them in reports produced to Plaintiffs, and they were used to cross examine Plaintiffs’ experts during discovery. Plaintiffs’ counsel never once objected that the documents were new or that they related to a new, previously unknown defense. Clearly, as Plaintiffs know, the Rainer evidence is not being offered as part of a new defense about which Plaintiffs have never before heard. First, Defendants are not raising a new legal defense at all. Defendants seek to use the Rainer evidence as additional support for the obviousness defense that they have pursued since the start of this case. One of the secondary considerations used to determine the knowledge of a person

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of ordinary skill in the art at the time of the invention is near-simultaneous invention.²

As the Federal Circuit has noted recently: “the fact of near-simultaneous invention, though not determinative of statutory obviousness, is strong evidence of what constitutes the level of ordinary skill in the art.” *Ecolochem, Inc. v. S. Cal. Edison, Co.*, 227 F. 3d 1361, 1379 (Fed. Cir. 2000). The Federal Circuit further stated that “the issue of simultaneous invention is directly tied to the level of knowledge attributable to one of ordinary skill in the art.” *Id.*

REDACTED it is well-established that near-simultaneous invention bears on the level of ordinary skill in the art and is highly relevant to the obviousness determination.³

Second, as noted below, Plaintiffs’ claims of surprise simply cannot be squared with the record in this case. In numerous different ways and at numerous different times, Defendants have asserted the relevance of Dr. Rainer to the issue of obviousness of the ‘318 patent.

A. Fact Discovery

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² At the pretrial conference, Plaintiffs’ counsel referred to near-simultaneous invention as a new defense. Ex. A. at 43. It is not. Defendants are not asserting that the Rainer evidence establishes prior invention under 35 U.S.C. §102(g) or any of the other statutory bar defenses under § 102. Near-simultaneous invention is not an independent grounds for invalidity. Rather it is one of many secondary considerations that the Court will consider in determining whether the patent-in-suit is obvious.

³ Barr included this case law in its pretrial submission as part of its Statement of Issues of Law. Ex. G at 3-5.

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B. Defendants' Expert Reports

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C. Depositions of Plaintiffs' Experts

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D. Hearing before Judge Jordan on August 30, 2006

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* * *

In the face of these disclosures, Plaintiffs resort to arguing that Defendants failed to answer or supplement their interrogatory answers to include reference to near-simultaneous invention. But Defendants had no obligation to do so as long as they disclosed the information elsewhere. F.R.C.P. 26 (e)(2).⁶

There is no question that Plaintiffs properly were placed on notice that Defendants intended to rely on the secondary consideration of simultaneous invention, based on Rainer and Waldheim, for purposes of the obviousness defense.

Plaintiffs plainly have known about the Rainer and Waldheim evidence and its relevance to the obviousness defense for months. Plaintiffs certainly could have raised any concerns that they had long before the pretrial conference. Alternatively, Plaintiffs could have asked the Court for leave to take Dr. Rainer's deposition. They did not do so. Instead, after intentionally ignoring the Rainer and Waldheim evidence for months, Plaintiffs in November 2006 first asserted that they would attempt to bar the Rainer in-house study on the grounds that it was not authentic. At that time, Defendants began their efforts to obtain the testimony of Dr. Rainer for authentication/foundational purposes.

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⁶ "(2) A party is under a duty seasonably to amend a prior response to an interrogatory . . . if the party learns that the response is in some material respect incomplete or incorrect and *if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing.*" F.R.C.P. 26(e)(2).

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In sum, the record makes it clear that Plaintiffs knew about Dr. Rainer and Waldheim and the purpose for which Defendants intended to use the evidence. Plaintiffs understood the relevance of the documents well enough to block at every step Defendants' attempts to talk to the author about them.⁹ In light of all this, it would be manifestly unfair to exclude such evidence. Defendants should be permitted to go forward with the trial deposition of Dr. Rainer.

Respectfully submitted,

/s/ John C. Phillips, Jr.
JOHN C. PHILLIPS, JR.

cc: Steven J. Balick, Esquire (w/enc.)
Frederick L. Cottrell, III, Esquire (w/enc.)
George F. Pappas, Esquire (w/enc.)
Alan Bernstein, Esquire (w/enc.)
Edward Filardi, Esquire (w/enc.)

Enclosure¹⁰

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¹⁰ Defendants intentionally omitted using the letters H, P, and W as exhibits.